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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,921	09/24/2001	Didier Raoult		3015

7590 01/28/2004

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EXAMINER	
BASKAR, PADMAVATHI	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,921	RAOULT ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *6-9 and 12-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 10 and 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12/5/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's response to restriction requirement filed on 10/14/03 is acknowledged. Claims 1-28 are pending in the application.

Priority

2. This application is a 371 of PCT/FR00/00754 03/24/2000 which claims foreign priority to FRANCE 99/03989, 3/26/1999, FRANCE 99/06679, 5/21/1999 under 35 U.S.C. 119(a)-(d) or (f).

Information Disclosure Statement

3 The IDS filed on 12/5/01 and 5/13/02 has been acknowledged and a signed copy of each is enclosed with this office action.

Election/Restriction

4. Applicant's elected Group I, claims 1-5, 10-11, 16-17 and 25-26 with traverse for prosecution.

The traversal is on the grounds that lack of unity invention is not established or demonstrated by the office action

A. Applicant asserts that there is a unity of invention present between Group I, III, IV, V and VI because the inventive concept of claim 1, that is, the bacterium *Tropheryma whippelii* responsible for whipple's disease is linked so as to form a single inventive concept. Group III is directed to antibodies raised against Tropheryma whippelii and such antibodies are defined with respect to the bacterium and antigens contained by the bacterium. Therefore, the antibodies share a technical relationship with bacterium and the antigens define over the prior art. Accordingly unity of invention exists.

Similarly applicant asserts that the group IV-VI drawn to methods that use the antibodies of Group III which share a technical feature with bacterium and applicant reminds the examiner

MPEP Appendix AI and states that unity of invention can exist between a substance (antibody) and the use of that substance. Therefore, group I and III –VI posses unity of invention.

However, the Examiner disagrees with the applicant and would like to bring applicant's attention to 35U.S.C.371 and the Examiner followed the restriction requirement under 35U.S.C.371.

Although the applicant's concept "bacterium" may link Group I, III, IV, V and VI such concept does not constitute a special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a) because the expression "special technical feature" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. Specifically Schoedon et al 1997 teach i.e., isolation of *Tropheryma whippelii* bacterium (see Journal Infectious diseases, 176; 672-677) responsible for Whipple's disease. Therefore, it does not constitute a special technical feature by definition. Therefore, there is no inventive concept in claim 1 and hence unity of invention is lacking in-group I. Therefore, the technical feature the linking the inventions I, III, IV, V and VI does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art.

The special technical feature of Group 1II is considered to be an antibody that share no common structure, function and property with Group I claims.

The special technical feature of Groups IV, V and VI is considered to be different methods using antibodies that share no common structure, function and property with Group I claims.

Accordingly, Groups 1- III-VI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

B. Like wise, The special technical feature of Group II and VII is considered to be nucleic acids that share no common structure, function and property with Group I claims.

Accordingly, Groups 1- II and VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

C. As there is a lack of unity between inventions the restriction requirement is proper.

II. Applicant asserts that there is no undue burden on the examiner for searching all claims 1-28.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of the Groups are different necessitating different searches of issued U.S. Patents. However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because, for example, search and examination issues for nucleic acids, antibodies are different and would not encompass protein. Additionally, it is submitted that the inventions of the separate Groups have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group.

The examiner regrets the oversight made on restriction requirement on 9/10/03 including claims 16-17 in inventions I and III. However, claims 16-17, drawn to a kit for serological diagnosis of whipple's disease should have been in invention V along with claim 13. Please note that claim 16 is depending from claim 13. Therefore, claims 13, 16 and 17, drawn to a kit and a method of serodiagnosis are placed rightly together in invention V.

Similarly, claims 25-26, drawn to a kit for serological diagnosis of Whipple's

disease should have been in invention VI along with claims 14-15. Please note that claim 25 is depending from claim 14. Therefore, claims 14-15 and 25-26, drawn to a kit and a method of serodiagnosis are correctly placed together in invention VI.

Again, the examiner regrets any inconvenience caused by this and would like to make the record clear. Claims 1-5 and 10-11 are under examination.

5. Claims 6-9, 12-28, are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement on 10/14/03.

Specification

6. This application has not followed the directions or order or arrangement in framing the specification as required in 37 CFR 1.77(b). For example: There is no brief description of the drawing as set forth in 37 C.F.R.1.74.

Claim Rejections - 35 USC 112, first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 3, 5 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete information for the deposit of the CNCM I-2202 and CNCM I-2411. It is not clear that the bacterium or hybridoma cell line is known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the bacterium or hybridoma cell lines of the invention, a suitable deposit for patent purposes, evidence of public availability of the cell lines of the invention or evidence of the reproducibility without undue experimentation of the monoclonal antibodies is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the hybridoma cell line described in the specification as filed is the same as that deposited in the

depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 5 is rejected as being vague and indefinite in the recitation of " molecular weights of about 35, 50, 60, 100 and 200 kD determined in Figures 2 and 3 by polyacrylamide gel electrophoresis □. In consideration of the discrepancies often encountered in the art between protein molecular weights when determined by different methods, whenever a molecular weight is recited to characterize a protein the claim should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions or whether reducing or non-reducing conditions were used.

Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because it fails to recite any process step that relates to the purpose set forth in the preamble.

Claim Rejections - 35 USC 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-2 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Schoedon et al 1997.

Claims are directed to Bacterium *Tropheryma whippelii* and antigen, said bacterium isolated and obtained from a culture of human fibroblasts after at least 2 months of incubation in a culture medium based on MEM.

Schoedon et al disclose isolation of *Tropheryma whippelii* bacterium (see Journal Infectious diseases, 176; 672-677) responsible for Whipple's disease (see abstract) from biopsy material obtained from a patient. The bacterium is cultured in medium containing (see figure1) deactivated mononuclear phagocytes (see page 673, right column, under inoculation of cultures)

Claim 2 " Bacterium obtained from a culture of human fibroblasts after at least 2 months of incubation in a culture medium based on MEM" is a product-by-process claim. Although product-by-process claims are limited and defined by the process, nonetheless, determination of patentability is based on the product itself. The patentability of a product does not depend upon its method of production. If the product in the product-by-process claim is the same as or an obvious variant of the product of the prior art, the claim is unpatentable even though the product was made by a different process. The recitation of a process limitation in claim 2 is not seen as further limiting the claimed product, as it is presumed the equivalent products can be obtained

by multiple routes. Where a product-by-process claim is rejected over a prior art product that appears to be identical, although produced by a different process, the burden is upon the applicants to provide evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Thorpe*, 227 U.S.P.Q. 964, 966 (Fed. Cir. 1985). *In re Marosi*, 218 U.S.P.Q. 289, 293-293 (C.A.F.C. 1983). *In re Best*, 195 U.S.P.Q. 430, 433 (C.C.P.A. 1977). *In re Brown*, 173 U.S.P.Q. 685, 688 (C.C.P.A. 1972).

Figure 5 would read on antigen of bacterium as periodic acid-Schiff inclusion in bacterium has been identified. The prior art anticipated the claimed invention.

Status of Claims

13. Claims 1-5 and 10-11 are rejected.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

1/21/04